MAY - 9 2000

510(k) SUMMARY

Submitted by: PSK Connectors Pty Ltd
PO Box 928
55 Marianne Way
Mount Waverley Vic 3149
Australia
Phone: +61 3 9887 7629

Contact Person: In USA: Brian Newton
In Australia: Lawrence Puszko

Date Prepared: 19 January 2000

Proprietary Name: PSK Endoscope Cleaning System

Common Name: PSK system

Classification Name: Accessories, cleaning brushes, for endoscope. Gastreoenterology

Predicate Devices: Terumo Hypodermic syringe
510(k) #K771205
Terumo Disposable Hypodermic Syringe
510(k) #K980181
Terumo Retractable Needle (RN) Syringe
510(k) #K953940

Description of the Device: The PSK Endoscope Cleaning System is made from medical grade silicone tubing and various medical connectors used in endoscopy. It uses an external suction unit to direct fluids and /or air through endoscope channels. User may select individual channels for cleaning. It is especially useful for blocked channels which can not be unblocked with traditional manual methods.
There are appropriate types for various models of Pentax, Olympus and Fujinon endoscopes.

Intended Use of the Device: The Pre-Cleaning System for Endoscopes is designed for flushing the channels of flexible fiberoptic and video GI endoscopes.

Technological Characteristics: Pre-Cleaning System is made from similar type of materials as the predicate devices.

Instead of manually connecting a syringe to a port on the endoscope, pushing a syringe until the channel is clear and repeating the same for all channels, the user connects the Pre-Cleaning System and an external suction unit just once. In a fraction of time compared with a traditional syringe method the endoscope is ready to continue the cleaning and disinfection process in automated endoscope reprocessor (AER).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2000

PSK Connectors Pty. Ltd.
c/o Mr. Brian Newton
President
The Scope Exchange
311 South Main Street
Kernersville, NC 27284

Re: K000216
Pre-Cleaning System for Endoscopes
Dated: April 14, 2000
Received: April 17, 2000
Regulatory Class: II
21 CFR §876.1500/Procode: 78 KOG
Regulatory Class: I
21 CFR §876.1500/Procode: 78 FEB

Dear Mr. Newton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

INDICATIONS FOR USE STATEMENT

510(k) Number: K000216

Device Name: Pre-Cleaning System for Endoscopes

Indications For Use: Pre-Cleaning System is used for flushing flexible gastrointestinal (GI) endoscopes prior to higher level disinfection/sterilization.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR §801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000216